holder of the registration is legally qualified to deal in such drugs.

[45 FR 38043, June 6, 1980, as amended at 48 FR 54007, Nov. 30, 1983; 52 FR 2682, Jan. 26, 1987; 55 FR 11577, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Drug Listing Branch (HFD–334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. In addition, there will be available for inspection at each of the FDA district offices the same information concerning firms within the geographical area of each district office. Upon request and receipt of a self-addressed stamped envelope, the Drug Listing Branch, Center for Drug Evaluation and Research or appropriate FDA district office will verify registration number or provide the location of a registered establishment.

(1) The following types of information submitted under the drug listing requirements will be available for public disclosure when compiled:

(i) A list of all drug products.

(ii) A list of all drug products arranged by labeled indications or pharmacological category.

(iii) A list of all drug products arranged by manufacturer.

(iv) A list of a drug product's active ingredients.

(v) A list of drug products newly marketed or for which marketing is resumed.

(vi) A list of drug products discontinued.

(vii) Labeling.

(viii) Advertising.

(ix) Information that has become a matter of public knowledge.

(x) A list of drug products containing a particular active ingredient.

(xi) A list of all code imprints.

(2) The following types of information submitted in accordance with the drug listing requirements will not be available for public disclosure (except that any of the information will be available for public disclosure if it has become a matter of public knowledge or if FDA finds that confidentiality would be inconsistent with protection of the public health):

(i) Any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the act.

(ii) A list of a drug product's inactive ingredients.

(iii) A list of drugs containing a particular inactive ingredient.

(b) Requests for information about registrations and drug listings of an establishment should be directed to Drug Listing Branch (HFD–334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or, with respect to the information described in paragraph (a) of this section, to the FDA district office responsible for the geographical area in which the establishment is located.

[45 FR 38043, June 6, 1980, as amended at 50 FR 8996, Mar. 6, 1985; 55 FR 11577, Mar. 29, 1990; 58 FR 47959, Sept. 13, 1993; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999]

§ 207.39 Misbranding by reference to registration or to registration number.

Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and constitutes misbranding.

Subpart D—Procedure for Foreign Drug Establishments

§ 207.40 Drug listing requirements for foreign drug establishments.

(a) Every foreign drug establishment whose drugs are imported or offered for import into the United States shall comply with the drug listing requirements in subpart C of this part, unless exempt under subpart B of this part, whether or not it is also registered.

(b) No drug, unless it is listed as required in subpart C of this part, may be imported from a foreign drug establishment into the United States except a drug imported or offered for import under the investigational use provisions of part 312 of this chapter. Foreign drug establishments shall submit the drug listing information in the English language.

(c) Every foreign drug establishment shall submit, as part of drug listing, the name and address of the establishment and the name of the individual responsible for submitting drug listing information. The establishment shall report to FDA any changes in this information at the intervals specified in § 207.30(a) for updating drug listing information.

[45 FR 38043, June 6, 1980, as amended at 55 FR 11577, Mar. 29, 1990]

PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

Subpart A—General Provisions

Subpart B—General Requirements for a Medication Guide

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 371, 374; 42 U.S.C. 262.

SOURCE: 63 FR 66396, Dec. 1, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 208.1 Scope and purpose.

(a) This part sets forth requirements for patient labeling for human prescription drug products, including biological products, that the Food and Drug Administration (FDA) determines pose a serious and significant public health concern requiring distribution of FDA-approved patient information. It applies primarily to human prescription drug products used on an outpatient basis without direct supervision by a health professional. This part shall apply to new prescriptions and refill prescriptions.

(b) The purpose of patient labeling for human prescription drug products required under this part is to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products.

(c) Patient labeling will be required if the FDA determines that one or more of the following circumstances exists:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects.

(2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product.

(3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

§ 208.3 Definitions.

For the purposes of this part, the following definitions shall apply:

(a) *Authorized dispenser* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

(b) *Dispense to patients* means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c) *Distribute* means the act of delivering, other than by dispensing, a drug product to any person.

(d) *Distributor* means a person who distributes a drug product.